PMA Memorandum

Subject: M020022/M002: Non-clinical testing

Device: X STOP Interspinous Process Distraction System ("X STOP")

Indications: The X STOP is indicated for patients aged 50 or older suffering from intermittent neurogenic claudication secondary to mild to moderate lumbar spinal stenosis at one or two levels, and who have undergone a regimen of non-operative treatment.

Sponsor: St. Francis Medical Technologies, Inc.

Contact: Yvonne Lysakowski
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[redacted]

Device Description

The X STOP Interspinous Process Distraction System is manufactured from Ti 6Al-4V ELI titanium alloy that conforms to ASTM Standard F136-96 (Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications). The device consists of two components: a spacer assembly and a wing assembly. The spacer assembly is comprised of a tissue expander, a fixed wing, and an oval spacer. The wing assembly is comprised of an adjustable wing and locking screw. After the spacer assembly is implanted, the wing assembly is attached, the width is adjusted, and the screw tightened with a torque-limiting hex-head screwdriver. The proposed principal behind the X STOP is that by distracting symptomatic spine segments and maintaining them in a slightly flexed position, symptoms of lumbar spinal stenosis can be relieved. (Note: In Amendment 3 of the PMA, the device is referred to as the X STOP Interspinous Process *Decompression* System.)

The X STOP is available in five sizes, with the size referring to the minor diameter of the oval spacer in the spacer assembly. (Engineering drawings are available in Attachment 2.1 of Module 2.)

Model	Description
1-1206	6mm X STOP Interspinous Process Distraction System
1-1208	8mm X STOP Interspinous Process Distraction System
1-1210	10mm X STOP Interspinous Process Distraction System
1-1212	12mm X STOP Interspinous Process Distraction System
1-1214	14mm X STOP Interspinous Process Distraction System

The device is implanted using an instrument set designed to work with the X STOP; it includes the following items:

1. Small dilator
2. Large dilator
3. Distractor
4. Spacer insertion instrument
5. Wing insertion instrument
6. Hex head screwdriver

Design versions

An original design of the implant device was used in a ten-patient pilot study from May of 1997 to April of 1998. An "unwelded" version of the device, in sizes up to 12mm, was implanted in 22 patients in a clinical trial that began in February 2000. The sponsor stopped the study in May 2000, after 5 device failures (loosening / disassembly of the Threaded Insert and Tissue Expander components) in the 22 study patients implanted with the device. Following a failure investigation that included testing of devices still in inventory, a manufacturing step was added to laser weld the Threaded Insert in place, to prevent the implant from disassembling once implanted. Additional, subsequent design modifications included an increased taper angle of the Tissue Expander, a more rounded Tissue Expander tip, redesign of the Threaded Insert / Tissue Expander connection, a modified Universal Wing design to allow for improved mating with the modified tissue expander, and a larger 14mm size. ***The pivotal study trial was conducted using this modified, "welded" version of the implant.***

Conformance to Performance Standards

The sponsor cites several standards to which it conforms:

ASTM F136-96: Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications

ASTM F2077-01: Test Methods for Intervertebral Body Fusion Devices

EN 1441: Medical Devices - Risk Analysis

EN 46001 Application of ISO 9001 to the Manufacture of Medical Devices

ISO 9001 Quality System

Pre-clinical Testing

Much of the pre-clinical testing was performed on the original, unwelded version of the device. Following the changes leading to the welded design, additional testing was performed to validate the new design. The test reports have been separated by the sponsor into two groups: mechanical and biomechanical. The mechanical tests include both static and fatigue tests to characterize the X STOP and determine its ultimate strength. The biomechanical tests were conducted to understand the relationship between the loads required to implant the X STOP, the *in vivo* loads experienced by the X STOP, and spinous process failure loads. Tests were also performed to evaluate the stability of the implanted X STOP when it is subjected to extreme loads. The test reports are included in a series of 32 attachments to section 4 (Non-Clinical Laboratory Studies) in M020022 Module 2.

FDA sent the sponsor a letter dated January 30, 2003, requesting additional information. Responses were submitted by the sponsor in a module amendment, M020022/M002/A001. Following review of the responses, FDA sent the sponsor a letter dated September 22, 2003, indicating that the module is accepted and is now considered closed.

The pre-clinical test reports submitted in Module 2 are briefly summarized below. The full test reports can be found in Binder 3 of the panel pack. The results in the test reports in Attachments 4-30 and 4-31 are part of the topic of FDA questions for the panel.

Attachment 4-1: Test Report B (Fatigue test)
This report includes cyclic compression fatigue loading of [redacted] X STOP [redacted] The peak compressive loads were [redacted] All [redacted] X STOP spacers ran out to 10 million cycles without failure. [redacted] release torques of the two threaded connections in the original X STOP assembly -- the side screw and the end screw. The results indicated that compression cycling had minimal effect on the release torque. [redacted] Finally, a finite element analysis was also conducted on the Universal Wing component.

Attachments 4-2 through 4-5: Test Reports 001, 001-01, 001-02, 001-03 (Explant analyses)
These reports detail the analyses of two explanted X STOP implants, as well as sample implants of the same original design, to determine the cause of the device failures (loosening of the implant). [redacted]

Attachment 4-6: Test Report 004-01 (Insertion forces)
This study was undertaken to measure the loads imparted on an X STOP implant during manual insertion in a cadaver model. [redacted]

Attachment 4-7: Test Report 002 (Laser-welded X STOP testing)
This report describes testing of the laser welded X STOP [redacted]

Axial tensile load tests were conducted [redacted] The test concluded that laser welding does not alter the tensile mechanical properties of the assembly. [redacted]

"Endurance tests" were conducted [redacted] The peak compressive loads were [redacted] The X STOP devices [redacted] achieved run out to 10 million cycles without failure. [redacted]

Torque release testing was performed [redacted] there was no cracking or visual change evident at the weld [redacted]

Simulated insertion tests were conducted on welded X STOP [redacted]

[redacted]

Attachment 4-9: Test Report 002-02 (Laser-welded X STOP testing)
The objective of this test was to measure the loads applied to the Mainbody(spacer)/Threaded Insert junction [redacted] lumbar motion segments [redacted] tested with appropriately sized X STOP implants [redacted] The average axial load on the Tissue Expander shaft during axial rotation of the motion segments was [redacted]

[redacted] Ten million cycles was achieved at a peak load [redacted]

Attachment 4-10: Test Report 002-03 (Fatigue testing of welded X STOP)
[redacted] X STOP implants were loaded [redacted] to 10 million cycles or until failure. [redacted] The results [redacted] suggested that [redacted] the Tissue Expander shaft is not likely to result in failure of the X STOP implant.

Attachment 4-11: Test Report 001-04 (repeated in Attachment 4-23: Stanford Report)
This report compares the insertion loads of the X STOP Tissue Expander with its original design [redacted] and its new design [redacted] The mean insertion load [redacted] was significantly less [redacted]

Attachment 4-12: Axial Pullout Testing
[redacted] the axial strength [redacted] X STOP implants [redacted] was tested. [redacted]

Attachment 4-13: Test Report 003-01 (Modified Tissue Expander)
These tests examined the impact of the change to the X STOP Tissue Expander [redacted] the existing design [redacted] and modified design [redacted] were selected for testing [redacted] all showed that the failure load was at least [redacted] greater than the expected physiologic loads.

Attachment 4-14: Test Report 003-04 (Modified Universal Wing)
The purpose of these tests was to evaluate the static and fatigue characteristics [redacted]

Attachment 4-15: Test Report 008-01 (FEA of 14mm X STOP)
A finite element analysis was performed on the [redacted] X STOP implant. [redacted]

Attachment 4-16: Test Report 003-02 (Modified engagement of Tissue Expander shaft and Spacer)
This test report evaluated the static and fatigue loading characteristics [redacted] the Tissue Expander shaft with the Main Body [redacted]

Attachment 4-17: Test Report 003-03 (Modified Threaded Insert)
A series of tests were conducted to evaluate the effects of modifications to improve the manufacturability of the laser weld process. The following static tests were performed on the modified X STOP and compared to similar testing [redacted]

Attachment 4-18: Test Report C (In vitro loads on spacer)
Data on expected in vivo loads between the spinous processes were measured during biomechanical testing at the University of Washington Biomechanical Lab. [redacted]

Attachment 4-19: Test Report A (In vitro loads vs spinous process failure strength)
An in vitro test was performed using X STOP spacers fitted [redacted] implanted into cadaveric lumbar motion segments. [redacted]

Attachment 4-20: Test Report 005-01 (In vitro loads vs spinous process failure strength)
The objective of these tests was to measure the in situ loads of an interspinous spacer, and relate these to the spinous process failure loads measured [redacted]

Each specimen was then disarticulated into individual vertebrae [redacted]

[redacted]

Attachment 4-21: Test Report D (Effect on ultimate strength of spinous processes)
[redacted] directed loads were applied to each of [redacted] vertebrae [redacted]

Attachment 4-22: Harrington Report 1 (X STOP loads, possible migration, spinous process strength)
[redacted] cadaveric specimens were used [redacted] determine the amount of load transmitted [redacted] investigate expulsion or migration [redacted] determine the static strength of the spinous processes [redacted] The results of protocol I indicated that the forces transmitted through the X STOP were [redacted] Protocol II revealed no cases of device expulsion. Protocol III showed no significant changes in the maximum applied force characteristics of the spinous process due to the presence of the X STOP.

Attachment 4-24: Test Report 004-02 (Lateral insertion forces and spinous process failure loads)
This study investigated the load required to implant the interspinous spacer (using ten lumbar motion segments) and compared the mean insertion load to the mean lateral spinous process failure load (measured using seven lumbar (L3-L5) cadaveric spine specimens). The mean lateral insertion load of the X STOP implant (66 ± 46 N; range: 11 - 150 N) was significantly less than the mean spinous process failure load (317 ± 197 N, range: 95 - 786 N). There was no significant difference between the mean failure loads of specimens loaded laterally in the cranial, middle, or caudal aspect of the spinous processes (335 ± 217 N, 309 ± 152 N, and 307 ± 241 N, respectively). There was a relationship between the vertebral bone mineral density and the spinous process failure load.

Attachment 4-25: Test Report 007-01 and Attachment 4-26: Test Report 007-01 Rev B
[redacted] This study was undertaken to reproduce in vitro the X STOP implant dislodgement [redacted] human cadaver specimens were tested at each interspinous process level, [redacted]

In all cases, the supraspinous ligament itself was intact and was not transected. In the remaining levels there was no displacement of the implant or fracture of the spinous process

Attachment 4-27: Test Report 007-02 (X STOP expulsion with flexion and extension)
This study was conducted to characterize the stability of the X STOP implant under extreme loading with proper implant placement
Each specimen was loaded with an axial force
The bending angle was for all levels in both flexion and extension

none of the implants displaced posteriorly or migrated. No spinous processes fractured or grossly deformed.

the surgical technique was modified to state that the X STOP implant must be placed in the concavity between the spinous processes, and not posterior to the apices of the spinous processes or in the space between the supraspinous ligament and the interspinous ligament. Surgeons are specifically instructed to remove part of the hypertrophied facet if the implant cannot be correctly positioned; if the facet is not significantly hypertrophied or its debulking does not permit a correct placement of the implant, the surgeon should consider aborting the procedure.

Attachment 4-28: Test Report 007-03 (X STOP expulsion with axial torsion)

This study was conducted to characterize the stability of the X STOP implant under extreme loading [redacted] an appropriately sized X STOP implant was inserted from the posterior direction into the interspinous space [redacted]

Each specimen was loaded with an [redacted] followed by clockwise (CW) and counter-clockwise (CCW) [redacted] After the [redacted] was tested, an appropriately sized implant was placed in [redacted] interspinous space, [redacted]

[redacted] implants were stable and did not dislodge [redacted] Pre- and post-test radiographs were taken [redacted] to identify any possible spinous process fractures or deformations; these indicated that no bony damage occurred [redacted] However, it is noted that this study did not employ the surgical technique suggested in the surgical technique manual; the technique used would be a worse case for dislodgement.

Attachment 4-29: Test Report 007-04 (X STOP stability with proper implant positioning)
This test report focuses on characterizing the stability of the X STOP implant in lumbar specimens with the implants placed in a proper position between the spinous processes, and loaded to extreme limits of axial torsion. [redacted] human cadaver specimens were tested with the [redacted] X STOP. [redacted] The initial incision in the interspinous ligament was made in the concave area of the interspinous space, anterior to the caudal and cephalad apices of the adjacent spinous processes; this method modeled the technique outlined in the Surgical Technique.

Each specimen was loaded with an [redacted], followed by clockwise (CW) and counter-clockwise (CCW) rotation angles [redacted] Following testing at each level, the implants were removed and the specimens were radiographed in the sagittal view.

None of the implants dislodged posteriorly or migrated, and there was no bony damage to the spinous processes. [redacted] Again, the surgical technique was modified to state that the X STOP implant must be placed in the concavity between the spinous processes, and not posterior to the apices

of the spinous processes or in the space between the supraspinous ligament and the interspinous ligament.

Attachment 4-30: Test Report 016-01 (Effect of X STOP on spinal and foramen dimensions)
The purpose of this study was to quantify the effect of the implant on the canal areas during flexion and extension. The sponsor hypothesized that, in extension, the canal area of the treated level would be greater than that of the intact specimen, and unaffected during flexion. They also hypothesized that the adjacent canal areas would be unaffected by the implant

Eight lumbar cadaver specimens (L2-L5) were placed in a custom acrylic frame capable of placing the specimens in a 1) neutral position, 2) 15° of flexion, or 3) 15° of extension. Once in the positioning frame, the specimens were placed in a 1.5 Tesla MRI scanner. Specimens were scanned in three positions (flexion, neutral, and extension) with and without the X STOP implant placed at the L3-L4 interspinous space. Axial slices were used to measure: 1) the canal area, 2) the lateral recess distance, and 3) the A/P canal depth at the L2/3, L3/4, and L4/5 levels. In addition, para-sagittal slices were used to measure: 1) the foramen area, 2) the foramen height, and 3) the foramen width at the L2/3, L3/4, and L4/5 levels.

Canal Area: At the L2-3 and L4-5 levels, there was no difference in the mean canal area between the intact and X STOP implanted specimens for a given position. The mean canal area did, however, decrease from flexion to extension for both the intact and implanted specimens. At the L3-4 level in the neutral and extended positions, the mean canal area of the X STOP implanted specimens was significantly greater than that of the intact specimens; there was no difference in flexion. Implanting the X STOP increased the mean area of the canal in extension by 18% (2.31 cm^2 to 2.73 cm^2).

Canal Diameter: Similar to the canal areas, there was no difference in the mean mid-sagittal canal diameter between the intact and X STOP implanted specimens for a given position at the L2-3 and L4-5 levels. The mean canal diameter did decrease from flexion to extension for both the intact and implanted specimens. At the L3-4 level extended position, the mean canal area of the X STOP implanted specimens was significantly greater than that of the intact specimens; there was no difference in flexion or neutral.

Subarticular Diameter: Similar to the previous two measurements, there were no differences in the mean subarticular diameter at the L2-3 or L4-5 levels. At the L3-4 level, however, the X STOP increased the diameter by 14% in the neutral position and 49% in extension.

Ligamentum Flavum: There were no consistent trends at either the adjacent or treated levels.

Foramen Area: At the L2-3 and L4-5 levels, there was no difference in the mean foraminal area between the intact and X STOP implanted specimens for a given position. The mean area did decrease from flexion to extension for both the intact and implanted specimens. At the L3-4 level in the extended position, the mean canal area of the X STOP implanted specimens was significantly greater than that of the intact specimens; there was no difference in flexion or neutral.

Foramen Height: Similar to the ligamentum flavum thickness, the foraminal height was not sensitive to changes in position or treatment.

Foramen Width: Similar to the lateral recess height in the axial view, the foramen width in the sagittal view was sensitive to position and treatment changes; in extension, the X STOP increased the foraminal width by 41%.

All of these results are summarized in the last two columns of the table below. (The four middle columns include literature data provided by the sponsor.) The sponsor states that these tests demonstrate that the X STOP implant prevents canal narrowing at the implanted level in extension. They also state that the X STOP does not alter the dimensions of the adjacent, intact levels, in the extended, flexed or neutral positions, although this data is not presented in the sponsor's report. The table shows that, in all cases except one (foramen height), the smallest dimension was measured without the X STOP present ("Current test Intact") and with the segment in a position of extension. With the segment in an extended position, the presence of the X STOP resulted in increased dimensions. (FDA notes that in the *flexed* segment position, the presence of the X STOP resulted in *smaller* values for all of the dimensions except foramen width, although the differences are not statistically significant.)

Table 1. Published Values of canal and Foramen Dimensions

Dimension	Position	Chung (2000)	Fujiwara (2001)	Inufusa (1996)	Schmid (1999)	Current test Intact	Current test with X STOP
Canal Area (mm^2)	Flex Ext	399 331		248 208	268 224	286 231	276 273
Canal Diameter (mm)	Flex Ext	25.0 23.0		20.2 17.7		19.3 17.8	19.0 19.5
Subarticular Diameter (mm)	Flex Ext	5.7 3.2		5.8 4.7		4.5 2.5	4.1 3.7
Lig Flay Thickness (mm)	Flex Ext	1.8 2.5		3.5 2.9	1.8 4.3	3.0 2.9	2.9 2.9
Foramen Area (mm^2)	Flex Ext		104 83.9	141 107	167 115	149 106	147 133
Foramen Height (mm)	Flex Ext		17.9 18.2	20.0 20.3		23.2 21.3	22.4 21.2
Foramen Width (mm)	Flex Ext		4.0 2.2	5.8 3.5		5.8 3.4	6.0 4.8

Attachment 4-31: Test Report 015-01 (Effect of X STOP on spinal kinematics)

A concern with the implantation of the interspinous spacer is that, by restricting flexion-extension at one motion segment level, the kinematics and loading of the adjacent levels may be altered, leading to degeneration and instability. This study investigated the use of the interspinous spacer on the kinematics of the lumbar spine. The sponsor hypothesized that the spacer will reduce the range of motion of the treated level in flexion-extension, while not affecting the treated level in axial rotation or lateral bending. They also hypothesized that the adjacent levels would not be affected.

Seven human lumbar (L2-L5) cadaver specimens were used for this testing. Each specimen was placed in a spinal loading frame capable of applying independent bending moments and axial loads. Labeled steel pins 10 cm in length were placed in each vertebra and on the upper and lower actuator to indicate the angular position. Two CCD cameras were used to record the position of the pins during the testing. Three images were taken during each test cycle: Neutral, Flexion or Left Bending/Rotation, and Extension or Right Bending/Rotation.

With a superimposed 700 N compressive force, specimens were initially tested intact by applying a ± 7.5 Nm bending moment in flexion and extension, left and right axial rotation, and left and right lateral

bending. Angle, force and torque data were recorded for each motion. Following the intact testing, the specimens were removed from the loading frame and an appropriately sized interspinous spacer was placed between the L3-L4 spinous processes in each specimen. The specimens were returned to the loading frame and the previously described loading regimen was applied to each specimen.

There was no significant difference between the mean range of motion of the intact and X STOP implanted specimens during axial rotation and lateral bending. During flexion/extension, however, the range of motion at the implanted L3/4 level was significantly reduced. The ranges of motion at the adjacent levels were not significantly changed. The results showed that placement of the interspinous implant in the specimen results in a 2° decrease in lordosis from L2-L5.

Attachment 4-32: Test Report 014-01 (Disc pressure)
This study investigated changes to intervertebral disc pressure at the level of X STOP instrumentation and at the adjacent disc levels above and below the level of insertion. The sponsor hypothesized that placement of an interspinous implant would result in a decrease in the intervertebral disc pressure at the level of instrumentation, without significantly affecting the disc pressures at the adjacent levels.

Eight cadaver lumbar spines were obtained from donors aged 56 to 80 years and stored at -22° C. The specimens were thawed and separated into motion segments consisting of 4 vertebrae (L2-L5) and 3 corresponding vertebral discs. Before testing, a compressive force of 300 N was applied to each specimen for 15 minutes with the spines placed in the neutral position; this step was to precondition the specimens and reduce any postmortem superhydration effects of the intervertebral discs.

A pressure transducer with a diameter of 1.3 mm was placed into the appropriate disc level with the tip just through the posterior annulus to allow for stress profilometry of the respective disc. A linear variable displacement transducer was used to measure the position of the pressure transducer as it was drawn through the disc. Both transducers were located on the same apparatus, allowing for simultaneous measurements of pressure and displacement.

Initially, each motion segment was placed in the loading frame in the neutral position and subjected to an axial force of 700 N for 30 seconds, after which time the pressure transducer was pulled along the midsagittal plane of the disc being measured. Both superior and lateral components of the compressive stress were measured by rotating the transducer needle 90 degrees during successive tests. Stress profilometry was performed for each disc (L2-L5) with the specimens in neutral, flexed, and extended positions. Flexion and extension were achieved by applying a 7.5 Nm bending moment in the respective direction with a superimposed 700 N compressive force.

An appropriately sized X STOP implant was then placed between the L3 and L4 spinous processes. The sequence described above was repeated with the specimens loaded in the neutral, flexed, and extended positions. Again, a transducer measured the intradiscal pressure during loading, and a displacement transducer measured the travel of the pressure transducer through the disc.

A total of 12 measurements were recorded for each disc level (6 each with and without the X STOP). The mean pressures were compared between the intact specimens and implanted specimens for a given level (L2-L3, L3-L4, L4-L5), specimen position (flexion, neutral, extension), transducer direction (superior, lateral), and disc region (posterior, nucleus, anterior). A total of 54 comparisons were made using individual paired t-tests each with a level of significance of 0.05.

As expected, the most notable differences in mean disc pressure were identified at the L3-L4 level. In extension, the mean pressure in the posterior annulus was significantly reduced with the use of the implant; the mean superior pressure was reduced by 63% and the mean lateral pressure was reduced

by 46%. The mean pressures in the region of the nucleus were significantly reduced after implantation; the mean superior pressure was reduced by 41% and the mean lateral pressure was reduced by 40%.

In the neutral position, the mean superior pressure in the posterior annulus was reduced by 38%, and the mean superior and lateral pressures in the nucleus were reduced by 20% and 17%, respectively.

There were no significant differences between the mean pressures of the intact and implanted specimens at the L2-L3 level. The only significant differences between the intact and implanted specimens at the L4-L5 were between the lateral nucleus pressures in the neutral (7%) and flexed positions (9%), and the lateral anterior annulus pressures in the extended position (12%).

Module 2/Amendment 2, Attachment 4: Test Report: 019-01 (X STOP Posterior Pullout Strength)

[redacted] the sponsor performed testing on [redacted] lumbar motion segments [redacted] the appropriate implant was placed in the [redacted] interspinous space, and the implant was pulled in a posterior direction [redacted] Appropriately sized implants were then placed in the posterior margin of the interspinous space, and the specimens were placed posterior and extended [redacted] The devices were also placed anteriorly, the specimens extended and the implants dislodged.

[redacted]

The sponsor stated that there was no significant difference in the pullout strength [redacted] and that it is very unlikely that the X STOP would experience a load of such magnitude and direction in flexion and extension. [redacted]

Conclusion

In summary, the sponsor has presented a series of test reports that describe the mechanical and biomechanical testing performed on the device [redacted] Following device modifications [redacted] additional testing was performed to validate the new design. The mechanical tests include both static and fatigue tests to characterize the X STOP and determine its ultimate strength. The biomechanical tests conducted in cadaver models were intended to understand the relationship between the loads required to implant the X STOP, the *in vivo* loads experienced by the X STOP, and spinous process failure loads. Tests were also performed to evaluate the stability of the implanted X STOP when it is subjected to extreme loads.

The sponsor's conclusions included the following: 1) The peak loads measured under 'physiologic' loading of the spinous processes with the X STOP in place are much less than the loads to failure of the spinous processes. FDA notes that the clinical incidence of spinous process fracture should support or refute this conclusion; clinical data will also be essential in evaluating the effects of repeated loading of the spinous processes over time. 2) Proper anterior placement of the X STOP,

within the concave space of the spinous processes, is essential to preventing dislodgement of the device and/or deformation of the spinous processes. 3) The X STOP implant prevents canal narrowing at the implanted level in extension, and does not alter the dimensions of the adjacent levels in the extended, flexed or neutral positions. FDA notes that the presence of the X STOP reduces all of the spinal and foramen dimensions (except foramen width) in the flexed position, although the differences are not statistically significant. The quantitative results for the adjacent spinal levels have not been presented. 4) There is no significant difference in the mean range of motion for an intact motion segment and an X STOP implanted segment during axial rotation and lateral bending. During flexion/extension, however, the range of motion at the implanted level is significantly reduced. The ranges of motion at the adjacent levels are not significantly changed. FDA notes that these results are based on studies using [redacted] cadaver specimens, and may not be indicative of changes seen clinically.

FDA welcomes comments from panel members regarding whether the clinical data support the pre-clinical testing conclusions related to the effects of the X STOP device on surrounding segments and/or spine biomechanics.